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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/431,843 | 11/02/1999 | IAN S. ZAGON | 13038 | 9285 |

7590 05/03/2005

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/431,843

Applicant(s)

ZAGON ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,6,14,16,17 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 38 is/are allowed.
- 6) ☒ Claim(s) 3,5,6,14,16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

1. Formal Matters

- A. The Amendment dated 1/25/05 has been entered into the record.
- B. Claims 1, 3, 5, 6, 14, 16, 17 and 38 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Specification

- A. The objection to the specification has been overcome in view of Applicants' amendment to Figure 9 in the Brief Description.

3. Claim Objections

- A. The objection to claim 5 has been withdrawn since the claim no longer depends from canceled claim 4.

4. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

- A. Claim 6 remains rejected under 35 USC 112, first paragraph, for the reasons already of record on page 4 of the Office Action mailed 10/28/04. Applicants argued that they have amended the claim to recite "isolated." However, this amendment does not appear in the claim.
- B. The rejection of claims 14, 16 and 17 under 35 U.S.C. 112, first paragraph, have been withdrawn in view of Applicants' arguments and Exhibit A demonstrating the use of the polynucleotide of the invention *in vivo*.
- C. Claims 3, 5, 6, 14, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated polynucleotides encoding SEQ ID NO:2, vectors and isolated host cells comprising these nucleic acids, does not reasonably provide enablement for isolated polynucleotides which hybridize to SEQ ID NO:1, or for compositions comprising these nucleic acids or vectors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The breadth of the claims is excessive with regard to Applicants claiming all polynucleotides which hybridize to SEQ ID NO:1 and bind OGF. The claims include variants of the polypeptide of SEQ ID NO:2. Applicants have not provided any guidance or working examples of these molecules. The specification provides no guidance as to what critical regions/residues of the encoded protein must be retained in order to allow for the functional requirement that the encoded receptor bind OGF. Given this lack of guidance, it would not be predictable to the artisan what regions must be retained in order to maintain the required binding function of SEQ ID NO:2, which is the only working example. Claim 6 is rejected since it depends from claim 3 as well as the fact that it does not recite "isolated host cells."

In summary, the breadth of the claims is excessive regarding all nucleic acid molecules which hybridize to SEQ ID NO:1. Applicants provide no guidance or working examples of these molecules, or for compositions comprising these molecules, or expression vectors. Furthermore, the sequence of these variants is unpredictable. For these reasons, the Examiner holds that undue experimentation is required to practice the invention as claimed.

5. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 3, 5, 6, 14, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. Nucleic acid molecules which "hybridize" to those polynucleotides encoding SEQ ID NO:1 would have one or more nucleic acid substitutions, deletions, insertions and/or additions to said polynucleotide. The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Although these types of changes are routinely done in the art, the specification and claims do not provide any information as to what changes should be made. Structural

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features that could distinguish compounds in the genus from others in the nucleic acid or protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO:1, or molecules which hybridize to the polynucleotides encoding this SEQ ID NOs alone are insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made.

6. Claim Rejections - 35 USC § 112, first paragraph – new matter

A. The rejection of claims 3, 5, 6, 14, 16 and 17 under 35 USC 112, first paragraph, regarding the hybridization conditions has been withdrawn in view of Applicants' amendment to claim 3 to recite hybridization conditions that are present in the original specification.

7. Conclusion


A. Claims 1 and 38 are allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 10 AM – 7 PM (eastern); alt F 10 AM – 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ROBERT S. LANDSMAN, PH.D
PRIMARY EXAMINER